

Exhibit 4

DECLARATION OF COLONEL TONYA RANS

I, Colonel Tonya Rans, hereby state and declare as follows:

1. I am currently employed by the U.S. Air Force as the Chief, Immunization Healthcare Division, Defense Health Agency – Public Health Directorate, located in Falls Church, Virginia. I have held the position since June 2017. I am a medical doctor and have been board certified in Allergy/Immunology since 2008 and was a board certified Pediatrician from 2001-2015.

2. In my current role, my responsibilities include directing a responsive, evidence-based, patient-centered organization promoting optimal immunization healthcare for all DoD beneficiaries and those authorized to receive immunizations from DoD. This includes assisting in policy development, providing implementation guidance and education, and engaging in clinical studies through clinical collaboration. The Defense Health Agency-Immunization Healthcare Division (DHA-IHD) routinely engages with the medical representatives from the military departments, U.S. Coast Guard, Joint Staff, Combatant Commands, and others to develop standardized immunization implementation guidance in accordance with published policy for consistency across DoD where possible.

3. I am aware of the allegations set forth in the pleadings filed in this matter. This declaration is based on my personal knowledge, as well as information made available to me during the routine execution of my official duties.

Coronavirus Disease 2019 (COVID-19)

4. As part of my official duties, I served as a member of the COVID-19 Vaccine Distribution Operational Planning Team (OPT), which was directed to develop and implement DoD's COVID-19 Vaccine Distribution plan. The Coronavirus Task Force (CVTF) provided

overarching guidance to the OPT. The OPT provided routine and ad hoc updates on COVID-19 vaccine deliveries, administration, and adverse events to the CVTF.

5. The virus that causes COVID-19 disease is SARS-CoV-2, a ribonucleic acid (RNA) virus from the Coronavirus family. Like any RNA virus, the SARS-CoV-2 virus mutates and evolves constantly and regularly as it infects and replicates in host cells. Mutations that are beneficial to the virus (i.e., make the virus more easily spread between hosts, evade the immune system) are integrated into the viral genome, thereby increasing “survival” and replication opportunity. This has been seen with the SARS-CoV-2 Delta variant, which is twice as contagious as previous variants while the Omicron variant and subvariants are considered to be more transmissible than the Delta variant.¹ However, not all mutations are beneficial to the virus – some can result in virus death and therefore do not infect the host. This is part of the normal biology cycle of all viruses.

6. The latest reports from the U.S. Centers for Disease Control and Prevention (CDC) indicate that the SARS-CoV-2 virus spreads when an infected person breathes out droplets and very small particles that contain the virus.² These droplets and particles can be inhaled by other people or land on their eyes, noses, or mouth. In some circumstances, viral particles may contaminate surfaces and then may be transmitted to another person by touching the contaminated surface followed by touching the eye, nose, or mouth. People who are closer than 6 feet from the infected person are most likely to get infected, especially in areas where there is poor ventilation.

¹ <https://www.yalemedicine.org/news/covid-19-variants-of-concern-omicron> last accessed July 6, 2022.

² <https://www.cdc.gov/coronavirus/2019-ncov/faq.html>, last accessed July 6, 2022.

7. COVID-19 disease can cause acute symptoms such as fever/chills, cough, shortness of breath, fatigue, muscle aches, headache, nausea, vomiting, diarrhea, loss of sense of smell or taste and/or sore throat. Symptoms appear 2-14 days (usually within 4-5 days) after viral exposure.³ The infection can affect people in different ways: from asymptomatic, to limited and mild (for 2-3 days) to more severe (such as trouble breathing, chest pain, inability to think straight and inability to stay awake). Even with the availability of aggressive medical management and ventilator support in an intensive care setting for those with severe symptoms, over 6.3 million have died worldwide.⁴ As of June 22, 2022, CDC reports that over 86 million individuals in the U.S. have been diagnosed with COVID-19 disease, over 4.8 million have been hospitalized, and over 1 million have died (approximately 3 in 1,000 in the total U.S. population of 330 million).⁵ Per the CDC, the elderly and those with underlying medical history of cardiovascular disease, diabetes, chronic respiratory, liver, or kidney disease, smoking, being overweight or obese, HIV, certain intellectual or developmental disabilities, pregnancy, substance abuse disorders, a weakened immune system, transplant recipients, or cancer are more likely to develop serious illness.⁶ However, it is a misguided belief that those who are otherwise young and healthy could not develop severe, or even fatal, disease. During the acute infectious stage, the virus causes inflammatory cell death, resulting in the release of pro-inflammatory cytokines (proteins which

³ <https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html>, last accessed July 6, 2022.

⁴ <https://covid19.who.int/>, last accessed July 6, 2022

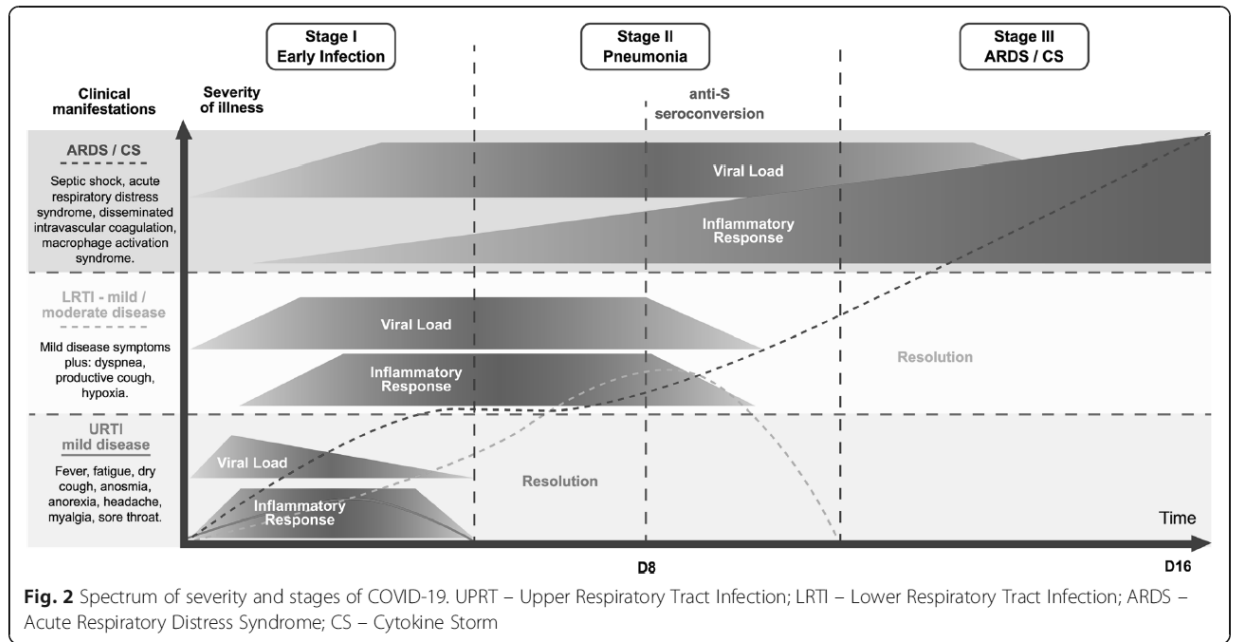
⁵ <https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html>, last accessed July 6, 2022.

⁶ <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>, last accessed July 6, 2022.

are important in cell signaling). Pro-inflammatory cytokines can cause inflammatory cell death within multiple organs. Cell death releases cellular and viral fragments, which results in production and release of more inflammatory cytokines.⁷ Disease progression can be curtailed by controlling the inflammatory process through immune system clearing of the virus. However, as depicted in the figure below, if the immune system is overwhelmed, either by viral immune evasive mechanisms or by an inadequate host response, the pro-inflammatory cytokine process may continue unabated, causing increasingly severe disease such as acute respiratory distress syndrome (ARDS) and cytokine storm. Recognition of the viral and hyperinflammatory phases informs treatment strategies for those with COVID-19 disease. Therapies that directly target the SARS-CoV-2 virus are anticipated to have the greatest effect early in the course of the disease, whereas immunosuppressive/anti-inflammatory/antithrombotic (anti-clotting) therapies are likely to be more beneficial after COVID-19 has progressed to stages characterized by low oxygen levels such as seen in ARDS.⁸

⁷ Bordallo B, et al. Severe COVID-19: What Have We Learned With the Immunopathogenesis? *Adv Rheumatol* (2020) 60(1):50. doi: 10.1186/s42358-020-00151-7.

⁸ <https://www.covid19treatmentguidelines.nih.gov/management/clinical-management/>, last accessed July 6, 2022.



8. The strongest recommendation for pre-exposure to COVID-19 disease remains vaccination, with highest level of evidence demonstrated through robust randomized control trials.⁹ In contrast, the efficacy and/or outcomes of COVID-19 disease treatments are variable and depend on a person's underlying medical history, genetics, the COVID-19 variant causing disease, immune response, and interval between symptom onset and treatment initiation. Only one outpatient therapy, remdesivir, has received FDA approval to date. Other therapies are administered under a FDA emergency use authorization.¹⁰ Just as it is acknowledged that there have been adverse events following COVID-19 vaccine receipt, it should also be understood that there are risks to COVID-19 disease treatment, even in those who are healthy enough to be managed in the outpatient setting. A non-exhaustive list of risks associated with COVID-19

⁹ <https://www.covid19treatmentguidelines.nih.gov/overview/prevention-of-sars-cov-2/>, last accessed July 6, 2022.

¹⁰ <https://aspr.hhs.gov/COVID-19/Therapeutics/Documents/side-by-side-overview.pdf>, last accessed July 6, 2022.

disease treatments includes cardiovascular and/or respiratory events, allergic reactions, fetal harm, and drug interactions. Further, some treatments must be administered shortly after diagnosis – within a matter of days – in order to be effective.¹¹

9. Although most people with COVID-19 are better within weeks of illness, some experience post-COVID-19 conditions, most commonly referred to as long-COVID. Long-COVID-19 conditions are generally considered to include a wide range of new, returning, or ongoing health problems occurring four or more weeks after infection, lasting for at least 2 months and are not explained by an alternative diagnosis. Those who were asymptomatic during their COVID-19 infection may develop long-COVID-19. At present, there is no diagnostic test or cure for long-COVID; instead, treatment is geared towards symptom management. An April 2022 Government Accountability Office publication reported that an estimated 10 to 30% of US COVID-19 survivors develop long-COVID, (7.7 million to 23 million people) with potentially over 1 million workers being out of the labor force at any given time.¹² One systematic review assessing outcomes from 8,591 long COVID-19 survivors with symptoms over 12 months found that fatigue/weakness (28%), breathing difficulties (18%), joint and muscle discomfort (26%), depression (23%), anxiety (22%), memory loss (19%), concentration difficulties (18%), and insomnia (12%) were the most prevalent symptoms at one-year follow-up, with female patients and those with more severe initial illness were more likely to suffer from the sequelae after one year.¹³ Another study comparing outcomes in patients referred to outpatient rehabilitation clinics

¹¹ *Id.*

¹² <https://www.gao.gov/products/gao-22-105666>, last accessed July 6, 2022

¹³ Han, Q, et al Long-Term Sequelae of COVID-19: A Systematic Review and Meta-Analysis of One-Year Follow-Up Studies on Post-COVID Symptoms. *Pathogens* 2022, 11, 269. <https://doi.org/10.3390/pathogens11020269>

after COVID-19 reported poorer general, mental, and physical health and functioning compared with patients with no previous diagnosis of COVID-19 referred for cancer rehabilitation. Those referred for rehabilitation following COVID-19 were more likely to be male, younger, and employed.¹⁴ A recent Department of Veterans Affairs study described long-term cardiovascular outcomes of 153,760 people with COVID-19 who survived the first 30 days after infection as compared with controls.¹⁵ They provided evidence that, beyond the first 30 days of infection, people with a history of COVID-19 exhibited “increased risks and 12-month burdens of incident cardiovascular diseases, including cerebrovascular disorders (i.e. stroke), dysrhythmias (abnormal heart rhythms), inflammatory heart disease (i.e. myocarditis, pericarditis), ischemic heart disease (decreased blood flow to the heart), heart failure, thromboembolic disease (blood clots that can break loose and occlude a blood vessel), and other cardiac disorders.” Of all cardiovascular diagnoses studied, the burdens of atrial fibrillation (AF) and heart failure (HF) were greatest. Risks of all cardiovascular disorders increased with severity of the acute COVID illness, with patients who required intensive care having particularly high risk. The authors report that the risks were evident regardless of age, race, sex, and other cardiovascular risk factors, including obesity, hypertension (high blood pressure), diabetes, chronic kidney disease, and hyperlipidemia (high cholesterol). Additionally, these risks were evident in people without any cardiovascular disease before COVID-19 exposure, “providing evidence that these cardiovascular risks might manifest even in people at low risk for cardiovascular disease.”¹⁶ A

¹⁴ Rogers-Brown JS, et al. CDC Morbidity and Mortality Weekly Report, Vol 70(27) 9 July 2021 <https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7027a2-H.pdf>.

¹⁵ Xie, Y., Xu, E., Bowe, B. *et al.* Long-term cardiovascular outcomes of COVID-19. *Nat Med* (2022). <https://doi.org/10.1038/s41591-022-01689-3>.

¹⁶ *Id.*

further study of multiple health care systems across the United States found that the incidence of cardiac complications after SARS-CoV-2 infection or mRNA COVID-19 vaccination were low overall but were significantly higher after infection than after vaccination for both males and females in all age groups.¹⁷

- Among males aged 12–17 years, the incidences of myocarditis and myocarditis or pericarditis were 50.1–64.9 cases per 100,000 after infection, 2.2–3.3 after the first vaccine dose, and 22.0–35.9 after the second dose; incidences of myocarditis, pericarditis, or multisystem inflammatory syndrome (MIS) were 150.5–180.0 after infection. Relative risk (RR) for cardiac outcomes comparing infected persons with first dose recipients were 4.9–69.0, and with second dose recipients, were 1.8–5.6; all RRs were statistically significant.
- Among males aged 18–29 years, the incidences of myocarditis and myocarditis or pericarditis were 55.3–100.6 cases per 100,000 after infection, 0.9–8.1 after the first vaccine dose, and 6.5–15.0 after the second dose; incidences of myocarditis, pericarditis, or MIS were 97.2–140.8 after infection. RRs for cardiac outcomes comparing infected persons with first dose recipients were 7.2–61.8, and with second dose recipients, were 6.7–8.5; all RRs were statistically significant.
- Among males aged ≥ 30 years, the incidences of myocarditis and myocarditis or pericarditis were 57.2–114.0 cases per 100,000 after infection, 0.9–7.3 after the first vaccine dose, and 0.5–7.3 after the second dose; incidences of myocarditis,

¹⁷ Block JP, et al. Cardiac Complications After SARS-CoV-2 Infection and mRNA COVID-19 Vaccination – PCORnet, United States, January 2021-January 2022, Vol 71, No. 14 April 8, 2022 <https://www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7114e1-H.pdf>

pericarditis, or MIS were 109.1–136.8 after infection. RRs or cardiac outcomes among infected persons compared with first dose recipients were 10.7–67.2, and compared with second dose recipients, were 10.8–115.2; all RRs were statistically significant.

Age group, yrs/ Outcome/ Risk window	Incidence* among males					Risk ratio (95% CI) SARS-CoV-2 infection versus mRNA COVID-19 vaccination				
	SARS-CoV-2 infection cohort†	mRNA COVID-19 vaccination cohort				mRNA COVID-19 vaccination cohort				Any dose**
		First dose‡	Second dose§	Unspecified dose¶	Any dose**	First dose‡	Second dose§	Unspecified dose¶	Any dose**	
5–11††										
Myocarditis										
7-day	12.6	0	0	0	0	NC	NC	NC	NC	NC
21-day	17.6	4.0	0	6.5	3.2	4.4 (0.5–35.7)	NC	2.7 (0.3–22.1)	5.4 (1.1–26.1)	
Myocarditis or pericarditis										
7-day	12.6	0	0	0	0	NC	NC	NC	NC	NC
21-day	17.6	4.0	0	6.5	3.2	4.4 (0.5–35.7)	NC	2.7 (0.3–22.1)	5.4 (1.1–26.1)	
Myocarditis, pericarditis, or MIS§§										
7-day	93.0	—¶¶	—	—	—	NC	NC	NC	NC	NC
21-day	103.0	—	—	—	—	25.7 (3.5–187.0)	NC	16.0 (2.2–116.0)	31.7 (7.7–131.2)	
42-day	133.2	—	—	—	—	33.3 (4.6–240.5)	28.2 (3.9–203.9)	10.3 (2.5–42.3)	20.5 (7.4–56.7)	
12–17††										
Myocarditis										
7-day	50.1	2.2	22.0	16.7	12.9	23.0 (5.3–99.5)	2.3 (1.2–4.4)	3.0 (1.3–6.7)	3.9 (2.1–7.0)	
21-day	59.0	3.3	26.7	20.4	16.0	18.0 (5.4–60.6)	2.2 (1.2–4.0)	2.9 (1.4–6.0)	3.7 (2.1–6.4)	
Myocarditis or pericarditis										
7-day	56.0	2.2	26.7	22.3	16.0	25.7 (6.0–110.3)	2.1 (1.1–3.9)	2.5 (1.2–5.2)	3.5 (2.0–6.1)	
21-day	64.9	3.3	35.9	29.7	21.6	19.8 (5.9–66.2)	1.8 (1.0–3.1)	2.2 (1.1–4.2)	3.0 (1.8–5.0)	
Myocarditis, pericarditis, or MIS§§										
7-day	150.5	—	—	—	—	69.0 (16.8–283.2)	5.6 (3.5–9.2)	6.8 (3.6–12.7)	9.4 (6.2–14.4)	
21-day	159.3	—	—	—	—	48.7 (15.2–155.7)	4.4 (2.9–6.9)	5.4 (3.1–9.4)	7.4 (5.0–10.8)	
42-day	180.0	—	—	—	—	4.9 (3.2–7.4)	4.6 (3.0–6.9)	5.4 (3.2–9.1)	4.9 (3.5–6.7)	
18–29										
Myocarditis										
7-day	55.3	0.9	6.5	7.0	4.6	61.8 (8.5–451.8)	8.5 (3.7–19.1)	7.9 (3.3–19.0)	12.0 (6.4–22.5)	
21-day	63.7	3.6	8.4	11.6	7.5	17.8 (6.4–49.8)	7.6 (3.7–15.7)	5.5 (2.7–11.0)	8.4 (5.0–14.2)	
Myocarditis or pericarditis										
7-day	85.5	2.7	12.1	22.0	11.5	31.8 (9.9–102.0)	7.0 (3.8–12.9)	3.9 (2.3–6.6)	7.4 (4.8–11.5)	
21-day	100.6	8.1	15.0	27.8	16.1	12.5 (6.2–25.2)	6.7 (3.9–11.7)	3.6 (2.3–5.8)	6.3 (4.3–9.1)	
Myocarditis, pericarditis, or MIS§§										
7-day	97.2	—	—	—	—	36.2 (11.3–115.5)	8.0 (4.4–14.6)	4.4 (2.6–7.4)	8.5 (5.6–12.9)	
21-day	112.3	—	—	—	—	13.9 (7.0–28.0)	7.5 (4.4–13.0)	4.0 (2.5–6.4)	7.0 (4.8–10.1)	
42-day	140.8	—	—	—	—	7.2 (4.5–11.4)	8.4 (5.0–13.9)	4.5 (2.9–6.9)	6.4 (4.6–8.8)	
≥ 30										
Myocarditis										
7-day	57.2	0.9	0.5	3.0	1.3	67.2 (31.4–143.8)	115.2 (42.6–311.7)	18.9 (11.2–31.7)	45.7 (30.2–69.2)	
21-day	63.0	1.9	1.2	4.2	2.2	32.4 (19.3–54.3)	50.8 (26.7–96.4)	15.1 (9.7–23.7)	28.3 (20.4–39.3)	
Myocarditis or pericarditis										
7-day	100.2	3.8	3.1	15.0	6.3	26.6 (18.2–38.7)	32.3 (21.3–48.8)	6.7 (5.2–8.6)	16.0 (12.9–19.8)	
21-day	114.0	7.3	7.3	20.1	10.4	15.6 (11.8–20.7)	15.6 (11.7–20.7)	5.7 (4.5–7.1)	10.9 (9.1–13.1)	
Myocarditis, pericarditis, or MIS§§										
7-day	109.1	—	—	—	—	28.9 (19.9–42.0)	35.1 (23.3–53.0)	7.3 (5.7–9.4)	17.4 (14.1–21.5)	
21-day	123.0	—	—	—	—	16.8 (12.7–22.3)	16.8 (12.7–22.2)	6.1 (4.9–7.7)	11.8 (9.9–14.0)	
42-day	136.8	—	—	—	—	10.7 (8.6–13.4)	10.8 (8.6–13.5)	5.4 (4.4–6.7)	8.7 (7.4–10.1)	

An additional study of patients enrolled in Veterans Affairs system found an increased risk of diabetes among those who had tested positive for COVID-19 when compared to contemporary and historical control groups. The review of millions of records found that people who had been diagnosed with COVID-19 were 46% more likely to develop Type 2 diabetes for

the first time.¹⁸ In order to further investigate medical issues of and treatment for those afflicted with long-COVID, on April 5, 2022, President Biden issued a Presidential Memorandum “directing the Secretary of Health and Human Services (HHS) to coordinate a new effort across the federal government to develop and issue the first-ever interagency national research action plan on Long COVID. The effort will advance progress in prevention, diagnosis, treatment, and provision of services, supports, and interventions for individuals experiencing Long COVID and associated conditions. The Presidential Memorandum also directs HHS to issue a report outlining services and supports across federal agencies to assist people experiencing Long COVID, individuals who are dealing with a COVID-related loss, and people who are experiencing mental health and substance use issues related to the pandemic.”¹⁹

COVID-19 Impacts on the Force

10. Infectious diseases have been the single greatest threat to the health of those involved in military operations. As the standard military unit shrinks and becomes more mobile to rapidly respond to global threats, any decrease in personal or unit readiness can significantly decrease operational efficiency and result in military ineffectiveness. Similar to other viruses, the SARS-CoV-2 virus can be easily transmitted to others prior to symptom development and therefore may infect significant numbers before being identified. DoD personnel, including service members, especially those in an operational setting (such as those working on ships, submarines, or engaged in the operation of aircraft and vehicles; those deployed to austere

¹⁸ Xie Y and Al-Aly Z. Risks and burdens of incident diabetes in long COVID: a cohort study *The Lancet, Diabetes and Endocrinology* Volume 10, Issue 5:311-321
[https://www.thelancet.com/journals/landia/article/PIIS2213-8587\(22\)00044-4/fulltext](https://www.thelancet.com/journals/landia/article/PIIS2213-8587(22)00044-4/fulltext).

¹⁹ <https://www.whitehouse.gov/briefing-room/statements-releases/2022/04/05/fact-sheet-the-biden-administration-accelerates-whole-of-government-effort-to-prevent-detect-and-treat-long-covid/>, last accessed July 7, 2022

environments; or those engaged in routine field training and airborne exercises) work in environments where duties may limit the ability to strictly comply with mitigation measures such as wearing a face mask, avoiding crowded areas, maintaining physical distancing of at least 6 feet, increasing indoor ventilation, maintaining good hand hygiene, and quarantining if in close contact with a COVID-19 case.²⁰ Therefore, upon exposure, these individuals may be at higher risk to be diagnosed with COVID-19 compared to those who can robustly maintain all recommended mitigation strategies. Further, although the elderly population and those with medical conditions are more likely to have severe disease, otherwise healthy Service members have developed long-COVID-19, potentially impacting their long-term ability to successfully perform their duties. Some service members have unfortunately succumbed to the disease, as described further below. Service members and federal civilian employees are the military's most valuable asset; without a medically ready force and ready medical force, the military mission is at high risk of failure. Recommendations from evidence-based medicine must remain the core approach to medical readiness. These evidence-based recommendations will continue to be updated as our understanding of the disease, complications, and impact from vaccination continues to evolve.

11. Between February 2020 and June 2022, there were 435,729 new and repeat cases of COVID-19 among active duty service members (**Table**). The largest monthly peak in cases occurred in January 2022, with 125,597 cases identified (**Figure**). The percentage of cases that were hospitalized was highest at the start of the pandemic and trended downward through

²⁰ The U.S. military's rapid response to the crisis in Ukraine and the surrounding areas serves as a prime example of the difficulty in not only predicting where and when service members will be required to serve, but also of the challenges in preventing the spread of COVID-19 and other diseases in undeveloped and austere environments. *See, e.g.*, <https://www.dvidshub.net/image/7065893/82nd-airborne-division-place-their-equipment-inside-tent-they-settle-their-new-location>, posted February 20, 2022.

January 2021. The percentage of hospitalized cases then increased from 0.9% in January 2021 to 1.9% in May and July 2021, and decreased to 0.4% in December 2021. The percentage of hospitalized cases remained low at 0.3% in January 2022 but increased to 0.9% in February 2022 and then dropped to 0.2% in June 2022. However, this recent trend should be interpreted with caution due to data lags. In total, 31 active duty service members have died from COVID-19 as of the end of June 2022. The number of active duty service members who died from COVID-19 remained very low throughout the first year of the pandemic, with a slight increase in the numbers of deaths occurring between December 2020 and February 2021, and a greater increase occurring between August and October 2021, coinciding with the increased spread of the Delta variant. More than one-half of the 31 deaths in active duty service members occurred between August and October 2021 (n=17). The most recently reported active duty service member death occurred in November 2021.

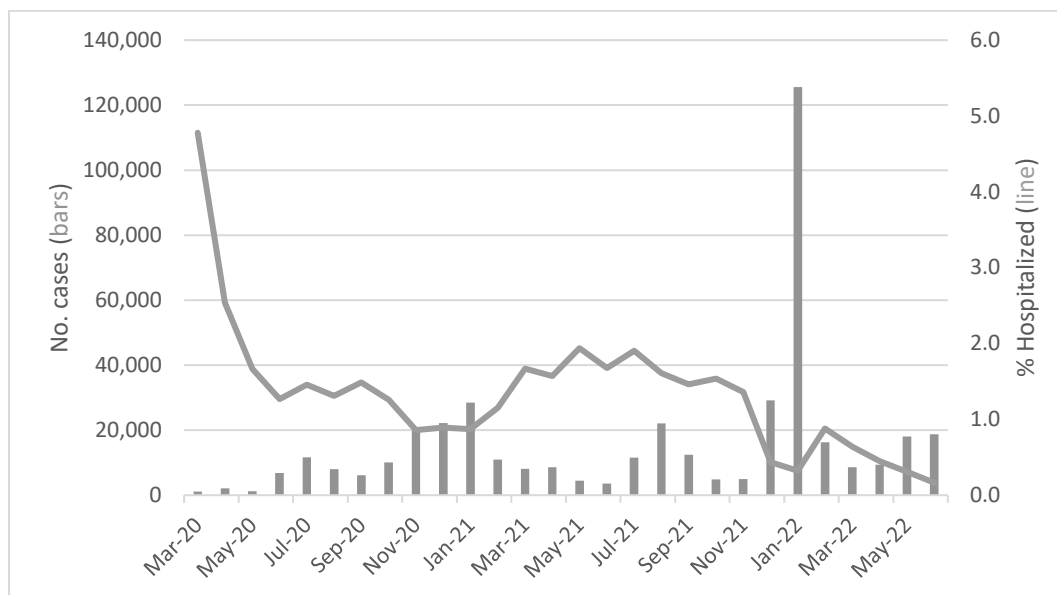
Table. COVID-19 cases, hospitalizations, and deaths among active duty service members, February 2020 - June 2022

	No. cases	No. hospitalizations	% hospitalizations	No. deaths
Feb-20	7	2	28.6	0
Mar-20	1,151	55	4.8	0
Apr-20	2,129	54	2.5	1
May-20	1,203	20	1.7	0
Jun-20	6,791	86	1.3	0
Jul-20	11,609	169	1.5	0
Aug-20	8,013	105	1.3	0
Sep-20	6,118	91	1.5	0
Oct-20	10,073	127	1.3	1
Nov-20	20,443	175	0.9	0

Dec-20	22,153	198	0.9	2
Jan-21	28,463	248	0.9	2
Feb-21	10,992	127	1.2	5
Mar-21	8,154	136	1.7	0
Apr-21	8,595	135	1.6	1
May-21	4,438	86	1.9	0
Jun-21	3,579	60	1.7	0
Jul-21	11,599	221	1.9	1
Aug-21	22,099	356	1.6	5
Sep-21	12,470	182	1.5	6
Oct-21	4,820	74	1.5	6
Nov-21	5,004	68	1.4	1
Dec-21	29,196	127	0.4	0
Jan-22	125,597	406	0.3	0
Feb-22	16,264	143	0.9	0
Mar-22	8,594	55	0.6	0
Apr-22	9,344	42	0.4	0
*May-22	18,087	56	0.3	0
*Jun-22	18,744	31	0.2	0

*Hospitalization and death data not complete due to data lags

Figure. COVID-19 cases among active duty service members and percentage of cases that were hospitalized, March 2020 – June 2022



Note: February 2020 is not shown due to the very small number of cases. Hospitalization data for May - June 2022 not complete due to data lags

12. Internally, DoD regularly updates its information concerning the number of vaccinations administered to the force and health impact of those who developed COVID-19 infections. Data through June 24, 2022 demonstrated that of the 665,332 COVID-19 cases within the DoD, 6,321 individuals were hospitalized and 689 have died, including 96 military service members (service members include Active Duty, Reserves, and National Guard personnel). In both the civilian sector and in the military, the overwhelming majority of individuals hospitalized or who died were unvaccinated or not fully vaccinated.

13. The bed capacity at DoD's military medical treatment facilities (MTFs) has generally followed local civilian hospital utilization, with some MTFs having high admission rates and a need to temporarily curtail medical services. Throughout the pandemic, the National Guard has been called on extensively to provide medical support to the civilian population. During the winter months, DoD had increasingly been deploying military doctors, nurses, paramedics and

other personnel to U.S hospitals to assist in preventing the country's medical system from collapsing from demand.

Vaccine Impacts

14. Immunizations are a global health and development success story, saving millions of lives across the age spectrum annually from illness, chronic conditions, and potentially death. Immunizations provide benefit at both the individual and community level. First, by stimulating an active immune response, vaccinated individuals are largely protected from serious outcomes associated with the disease of concern. Second, when a high proportion of individuals are immune (i.e., herd immunity) human-to-human transmission is disrupted, thereby protecting those who remain susceptible (i.e., those who may not be able to receive a vaccine or do not mount an adequate antibody response). Disease prevention through immunization also mitigates the need for pharmacologic treatment, reducing the risk of drug-drug interactions or adverse reactions to the treatment.

15. A key component of primary health care, the U.S. Food and Drug Administration (FDA) provides regulatory allowance for immunizations and has licensed vaccines for over 20 different infectious diseases. The Advisory Committee on Immunization Practices (ACIP), an advisory committee of the CDC, develops recommendations on how to use vaccines to control diseases in the United States. The military also maintains awareness, surveillance, and provides guidance to DoD personnel and beneficiaries on vaccine-preventable diseases in the global setting.

16. The COVID-19 vaccines developed using mRNA technology have resulted in several inaccurate claims.

- An initial claim is that mRNA vaccine clinical trials have never been studied in humans prior the implementation of mRNA COVID-19 vaccines. However, mRNA

vaccines are and have been in various clinical trial phases for diseases such as influenza, Zika, rabies, and cytomegalovirus, with the earliest study starting in 2013 (rabies).²¹ The consideration of mRNA technology use continues to expand. In March 2022, the National Institutes of Health launched a clinical vaccine trial using mRNA technology for those with Human Immunodeficiency Virus (HIV).²² Outside of vaccines for infectious diseases, lipid nanoparticle-mRNA vaccines are also in clinical trials for those with certain cancers, such as melanoma, ovarian cancer, and breast cancer.²³

- A second claim is that the mRNA in the COVID-19 vaccines can alter our DNA. The COVID-19 vaccine mRNA is encased in a lipid nanoparticle which is taken up by the cell. The mRNA is then translated to a protein for recognition by our immune system in the cytoplasm of the cell. DNA is not found in the cytoplasm – it's in the nucleus of the cell. For mRNA to get into the nucleus, it has to cross the nuclear membrane but it does not have a nuclear access signal to do so.²⁴

- A third claim is that COVID-19 vaccine mRNA technology is gene therapy, subject to different FDA safety requirements than what was conducted. However, the mRNA COVID-19 vaccines are not gene therapy. The companies Pfizer-BioNTech and Moderna developed their respective vaccines using a piece of genetic code from the SARS-CoV-2

²¹ <https://clinicaltrials.gov/>, last accessed July 7, 2022

²² <https://www.nih.gov/news-events/news-releases/nih-launches-clinical-trial-three-mrna-hiv-vaccines>, posted March 14, 2022.

²³ <https://clinicaltrials.gov/ct2/results?cond=cancer&term=mRNA+vaccines&cntry=&state=&city=&dist=&Search=Search>, last accessed July 6, 2022

²⁴ <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mrna.html>, last accessed July 7, 2022

virus to elicit an immune response in recipients. This is not the same thing as gene therapy, which restructures nucleic acids (DNA and RNA) to (potentially) cure disease. In gene therapy, a faulty gene is replaced with a functional gene. This is not to say that gene therapy does not exist. Clinical trials of gene therapy have shown some success in treating certain diseases, such as severe combined immune deficiency (i.e. “bubble boy” disease), hemophilia, and leukemia. Vaccines that use mRNA technology are not gene therapies because they do not alter a person’s genes. A February 2022 study which reported the ability to reverse transcribe the Pfizer COVID-19 mRNA vaccine *in vitro* into a human liver cell line²⁵ followed a May 2021 study by Zhang who reported that SARS-CoV-2 RNA (from the disease, not the vaccine) can be reverse transcribed and integrated into the genome of human cells.²⁶ The study design by Zhang and colleagues was challenged and to date his findings have not yet been duplicated.^{27,28} The study by Alden, who suggests that the Pfizer COVID-19 mRNA vaccine could be reverse transcribed in to the human

²⁵ Alden M, et al. Intracellular Reverse Transcription of Pfizer BioNTech COVID-19 mRNA Vaccine BNT162b2 In Vitro in Human Liver Cell Line. *Curr. Issues Mol. Biol.* 2022, 44, 1115-1126. <https://doi.org/10.3390/cimb44030073>.

²⁶ Zhang L, et al. Reverse-transcribed SARS-CoV-2 RNA can integrate into the genome of cultured human cells and can be expressed in patient-derived tissues. *Proc. Natl. Acad. Sci. USA* 2021, 118, e2105968118. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8166107/pdf/pnas.202105968.pdf>.

²⁷ Parry R., et al. No evidence of SARS-CoV-2 reverse transcription and integration as the origin of chimeric transcripts in patient tissues, *Proc. Natl. Acad. Sci.* 118 (33) e2109066118, August 3, 2021 <https://www.pnas.org/doi/10.1073/pnas.2109066118>.

²⁸ Kazachenka A, and Kassiotis G. SARS-CoV-2 Host Chimeric RNA-Sequencing Reads to Not Necessarily Arise From Virus Integration Into the Host DNA *Front. Microbiol.*, 02 June 2021 | <https://doi.org/10.3389/fmicb.2021.676693>.

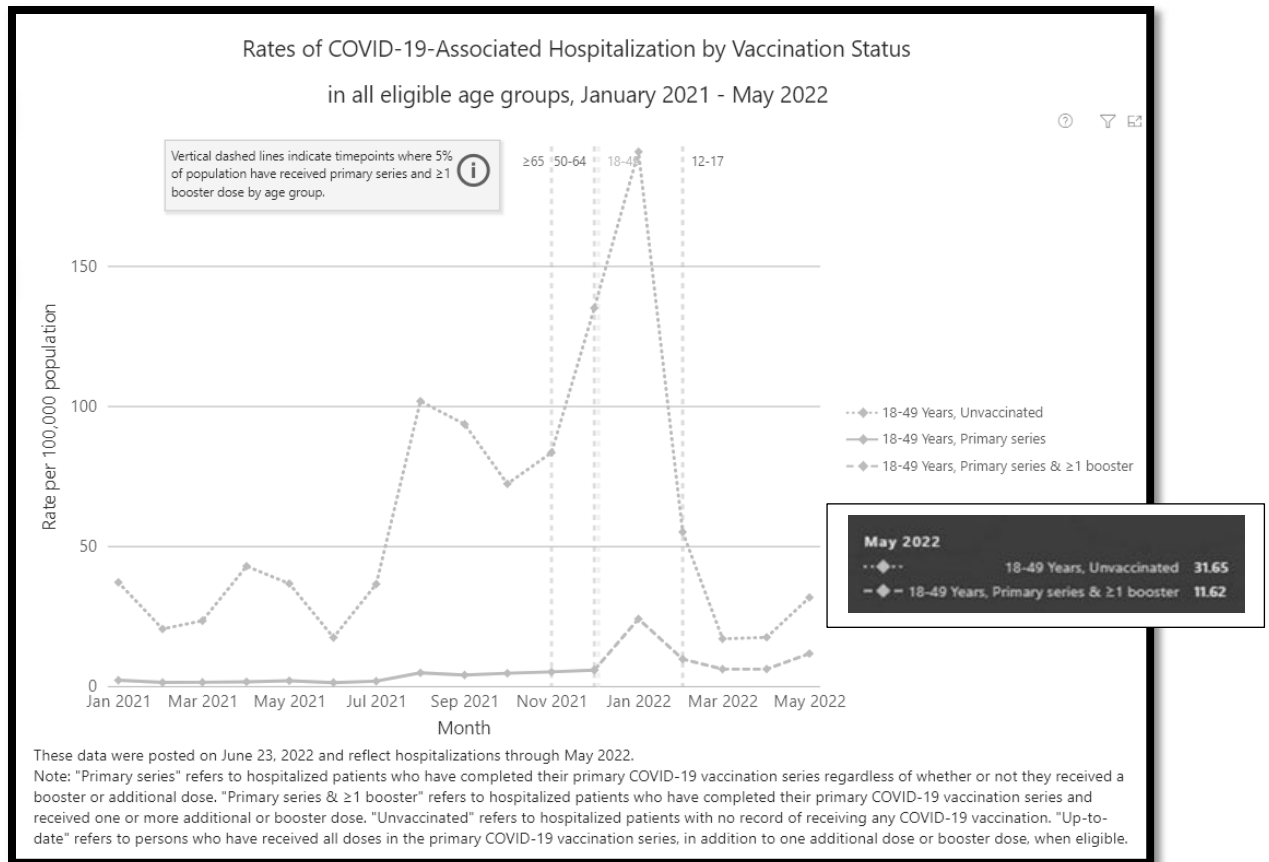
liver cell line, was quickly challenged as well.²⁹ First, the study involved a liver cancer cell line, which is not representative of normal cells. Additionally, the amount of vaccine used in the experiment (2 mcg/mL of vaccine to 200,000 cells) is far higher than the amount of vaccine adults receive through the vaccination (30 mcg/dose to the individual, made up of trillions of cells). Next, the study does not show evidence of uptake in the nucleus, where DNA is located. Rather, uptake was only seen in the cytoplasm (which is outside the nucleus). In summary, there is no evidence that mRNA COVID-19 vaccine alter a person's genes.

17. According to the CDC, over 596 million doses of COVID-19 vaccine have been given in the United States from December 14, 2020, through June 29, 2022.³⁰ Evidence consistently shows that the incidence of COVID-19-associated hospitalizations and deaths are higher in unvaccinated than vaccinated persons, even in Omicron predominance. In May 2022, , the rate of COVID-19 associated hospitalizations in unvaccinated 18-49 year olds was 31.6 per 100,000 and the rate of COVID-19 associated hospitalization in those who received primary series and at least one booster was 11.6 per 100,000.³¹

²⁹ Merchant HA, Comment on Aldén et al. Intracellular Reverse Transcription of Pfizer BioNTech COVID-19 mRNA Vaccine BNT162b2 In Vitro in Human Liver Cell Line. *Curr. Issues Mol. Biol.* 2022,44, 1115–1126
<https://safe.menlosecurity.com/doc/docview/viewer/docN754220A02DC32e462aaa249407362c1dc12a6e06fe2cbeb2a5768306187446bfe7510b679f45>

³⁰ <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html>, last accessed July 7, 2022.

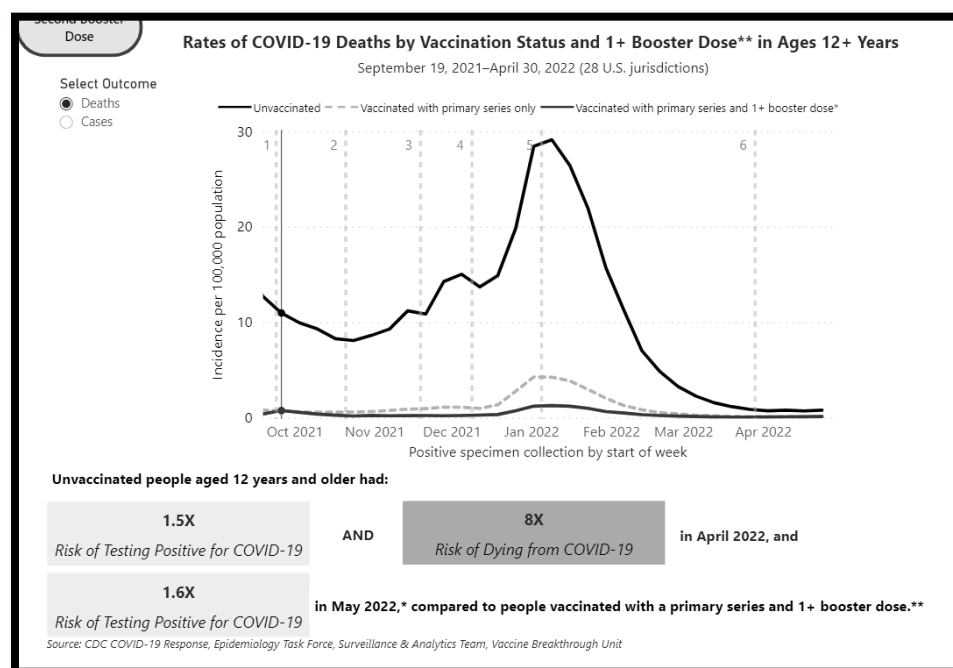
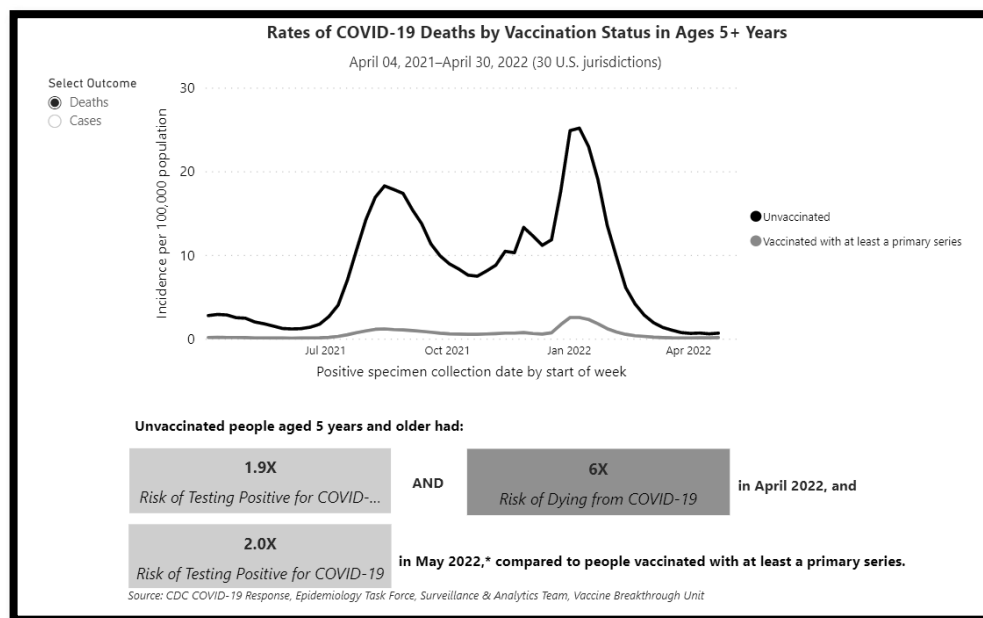
³¹ <https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalizations-vaccination>, last accessed July 7, 2022.



According to CDC, in April 2022 unvaccinated persons 5 years of age and older had a 1.9 times greater risk of testing positive for COVID-19 and a 6 times greater risk of dying from COVID-19 compared to people vaccinated with at least a primary series, and unvaccinated persons 12 years of age and older had a 1.5 times greater risk of testing positive for COVID-19 and 8 times greater risk of dying from COVID-19 compared to people vaccinated with a primary series and 1+ booster dose.³² In May 2022, unvaccinated persons aged 5 years and older had a 2.0 times greater risk of testing positive for COVID-19 compared to people vaccinated with at least the primary series and

³² <https://covid.cdc.gov/covid-data-tracker/#rates-by-vaccine-status>, last accessed July 7, 2022.

those unvaccinated persons 12 years of age and older had a 1.6 times greater risk of testing positive for COVID-19 compared to people vaccinated with a primary series and 1+ booster dose.³³



³³ *Id.*

18. As of July 6, 2022, DoD immunization sites have administered over 7.9 million doses of COVID-19 vaccine. Adverse events temporally associated with vaccine administration are centrally captured by CDC and FDA's Vaccine Adverse Event Reporting System (VAERS) through passive surveillance, meaning that information is voluntarily reported by health care providers and the public. VAERS is not designed to determine whether a vaccine caused a health issue of concern, but it is useful for detecting unexpected patterns of adverse event reporting that might indicate a possible safety problem with a vaccine. As of May 27, 2022, a total of 8,985 unique VAERS reports associated with COVID-19 vaccine (approximately 11 VAERS reports/10,000 doses administered) were submitted by DoD beneficiaries or those authorized to receive vaccine from DoD. Note that the number of VAERS reports/10,000 doses administered for DoD beneficiaries is likely to be lower, as the denominator does not take into account beneficiaries who receive vaccine in the civilian sector though DoD would still receive their VAERS report if the submitter indicated military affiliation. Additionally, individuals who had an adverse event but did not submit a VAERS would not be known and therefore would not be counted. It must be stressed that a VAERS submission to the CDC does not mean that the vaccine of concern caused or contributed to the medical issue reported.

19. The DoD has received hundreds of thousands of Pfizer-BioNTech BLA-compliant, EUA-labeled COVID-19 vaccine doses and continues to use them. On May 20, 2022 Pfizer-BioNTech's Comirnaty-labeled vaccine became available for ordering. To date, DoD has received over 42,000 doses within its supply chain and there are no restrictions to ordering this product.

20. Approach to immunizations within DoD are outlined in DoD Instruction 6205.02, "DoD Immunization Program" dated June 19, 2019, which states that it is DoD policy that all DoD personnel and other beneficiaries required or eligible to receive immunizations will be offered

immunizations in accordance with recommendations from the CDC and its ACIP. Army Regulation 40-562, Navy Bureau of Medicine and Surgery Instruction 6230.15B, Air Force Instruction 48-110_IP, Coast Guard Commandants Instruction M6230.4G, “Immunizations and Chemoprophylaxis for the Prevention of Infectious Diseases,” October 7, 2013, further states the Military Service policy concerning immunizations follows the recommendations of the CDC, ACIP, and the prescribing information on the manufacturer’s package inserts, unless there is a military-relevant reason to do otherwise. This document also describes general examples of medical exemptions, which include “evidence of immunity based on serologic tests, documented infection, or similar circumstances.” Some interpret this as a diagnosis of COVID-19 disease and/or results of a COVID-19 serologic test means that a medical exemption should be granted. However, of significance is the phrase “evidence of immunity.” CDC defines immunity as “protection from an infectious disease. If you are immune to a disease, you can be exposed to it without becoming infected.”³⁴ There are two major types of testing available for COVID-19: diagnostic tests, which assess for current infection, and antibody tests, which assess for antibody production, which is indicative of past infection and (in some tests) a history of vaccination. The FDA states, “Antibody tests should not be used to diagnose a current SARS-CoV-2 infection or COVID-19 and, at this time, should also not be used to check for immunity. More research is needed to determine what, if anything, antibody tests can tell us about a person’s immunity.”³⁵ As described below, the manufacturers of the lab tests also state that it is unclear at this time if a

³⁴ <https://www.cdc.gov/healthyschools/bam/diseases/vaccine-basics.htm>, last accessed July 7, 2022.

³⁵ <https://www.fda.gov/consumers/consumer-updates/coronavirus-disease-2019-testing-basics>, last accessed July 7, 2022.

positive antibody result infers immunity against future COVID-19 infection. Therefore, given the scientific evidence available, a medical exemption based on the history of COVID-19 disease or serology results does not meet “evidence of immunity.” The presence of antibodies is not the same thing as being immune.

21. The CDC states that “COVID-19 vaccination is recommended for everyone ages 6 months and older, regardless of a history of symptomatic or asymptomatic SARS-CoV-2 infection. This includes people with prolonged post-COVID-19 symptoms and applies to primary series doses and booster doses. This recommendation also applies to people who experience SARS-CoV-2 infection before or after receiving any COVID-19 dose. Growing epidemiologic evidence indicates that vaccination following infection further increases protection from subsequent infection and hospitalization, including in the setting of increased circulation of more infectious SARS-CoV-2 strains...Viral testing to assess for acute SARS-CoV-2 infection or serologic testing to assess for prior infection is not recommended for the purpose of vaccine decision-making.”³⁶

22. Further, CDC states “antibody testing is not currently recommended to assess the need for vaccination in an unvaccinated person or to assess immunity to SARS-CoV-2 following COVID-19 vaccination. If antibody testing was done, vaccination with the primary series, an additional dose, or a booster dose should be completed as recommended regardless of the antibody test result. SARS-CoV-2 antibody tests currently authorized under an Emergency Use Authorization have variable performance characteristics and limitations. Furthermore, serologic

³⁶ https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html, last accessed July 7, 2022.

correlates of protection have not been established and antibody testing does not evaluate the cellular immune response.”³⁷

23. Although natural infection for some diseases, in some cases, can result in long-standing immunity (e.g., measles), there is risk of untoward outcomes from the disease itself, which can be chronic or even fatal. Examples include Pneumonia or invasive group B Strep from chickenpox, meningitis or epiglottitis from *Haemophilis influenza* type B, birth defects from rubella, liver cancer from Hepatitis B, and death from measles.

24. Examples of natural infections that do not mount long-standing immunity include, in addition to COVID-19, Influenza, Respiratory Syncytial Virus, Malaria, Whooping cough, and rotavirus. In other words, re-infection is possible. Multiple serotypes of a pathogen like what is seen with influenza, and likely with the COVID-19 variants, also make determination of a protective serologic level more difficult, especially to say there is lifelong immunity.

25. “Herd immunity” is an epidemiologic concept that explains how a community may be protected from an infectious disease that is human-to-human transmitted.^{38,39} Herd immunity can be achieved through vaccination or through natural infection, if enough individuals 1) survive the disease and 2) mount a life-long immune response. Safe and effective vaccines are unequivocally considered the safer approach to a vaccine-preventable disease as compared to the

³⁷ *Id.*

³⁸ Desai AN, Majumder MS. What Is Herd Immunity? *Journal of American Medical Association*. 2020;324(20):2113. doi:10.1001/jama.2020.20895.

³⁹ McDermott A. Core Concept: Herd Immunity is an Important-and Often Misunderstood-Public Health Phenomenon. *Proc Natl Acad Sci U S A*. 2021;118(21):e2107692118. doi:10.1073/pnas.2107692118.

unpredictable response that an individual may have to exposure to disease, as described above. When a large proportion of a community is immune, vulnerable members of the community are indirectly protected because their chance of infection exposure is very low. Herd immunity does not eliminate risk, but the phenomenon means that population risk is greatly reduced. Herd immunity is only possible when humans are the only source of infection transmission, when immunity can be clearly established to prevent lifelong infection and transmission, and when an adequate proportion of the population can safely develop immunity to protect all others. Barriers to classical herd immunity with COVID-19 include frequent mutations in the SARS-CoV-2 virus, asymptomatic transmission, limited duration of protection provided by infection and/or vaccination, and resistance to vaccination in addition to other public health efforts.⁴⁰ Measles (rubeola virus infection) is a classic example of the successful application of the concept of herd immunity. It is important to recognize that there is no disease where a successful vaccination program would cease once a certain level of immunity is reached, unless the disease is considered eradicated (i.e. smallpox in humans). The CDC recommends children continue to receive routine immunizations for diseases that we have not seen in this country for many years (i.e., polio) or rarely see (i.e. epiglottitis from *Haemophilus influenza*) so the vaccine preventable disease does not resurge. The Department of Defense vaccine program follows these same principles.

26. The percentage of the population needing to be immune to drive herd immunity varies from disease to disease. Generally, the more contagious a disease is, the greater proportion of the population needs to be immune to stop its spread. For example, with regards to the highly contagious measles disease, approximately 95% immunity within a population is needed to

⁴⁰ Morens DM, et al. The Concept of Classical Herd Immunity May Not Apply to COVID-19. *The Journal of Infectious Diseases* 2022; jiac109, <https://doi.org/10.1093/infdis/jiac109>

interrupt the chain of transmission. When the immunity levels of a population falls, local outbreaks can, and have, occurred. In 2019, 1,282 individual cases of measles were confirmed in 31 states, the highest level since 1992. The majority of those cases were among those who were not vaccinated.^{41,42}

27. The herd immunity threshold – the level above which the spread of disease will decline – is currently unknown for COVID-19. As described above, in order to interpret an immunological (antibody or cellular) response from disease or vaccination through testing, a correlate of protection (CoP) must be determined and validated. No FDA antibody test has validated a correlate of protection at this time and none of them are licensed. At present, there are no commercially available COVID-19 tests to assess cellular response. A systematic review of 25 articles on whether a humoral (antibody) correlate of protection exists for SARS-CoV-2 was published in April 2022. The authors concluded “mixed evidence regarding a SARS-CoV-2 CoP, with a lack of standardization between laboratory methodology, assay targets, and sampling time points complicating comparisons and interpretation...individual-level data provided contradictory findings (those with high antibody levels may still be reinfected).”⁴³ Nonetheless, it is generally agreed that the more severe the COVID-19 disease is in an individual, the more antibodies a survivor would produce and therefore likely would have a higher degree of protection and possibly be protected longer than those who are asymptomatic or with mild symptoms.

⁴¹ <https://www.cdc.gov/measles/cases-outbreaks.html>, last accessed July 7, 2022.

⁴² National Update on Measles Cases and Outbreaks — United States, January 1–October 1, 2019. Vol 68 No 40 <https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6840e2-H.pdf>

⁴³ Perry J, et al. Does a humoral correlate of protection exist for SARS-CoV-2? A systematic review. PLoS ONE 17(4): e0266852 <https://doi.org/10.1371/journal.pone.0266852>

28. Those who receive the COVID-19 vaccine contribute to the information available from studying the outcomes from 596 million doses administered in the US and over the 12.1 billion doses administered globally.⁴⁴ Antibody response to vaccination is more consistent and there is minimal risk compared to the potential long-term complications and treatments needed to manage COVID-19 disease and its consequences. Although breakthrough infections do occur depending on the circulating variant and the longer the interval from vaccination, COVID-19 vaccines (especially when indicated boosters are received) remain highly effective in preventing hospitalizations and death.⁴⁵

29. Debate continues about whether natural immunity versus vaccine-induced immunity is more safe and protective against outcomes from breakthrough infections (a reinfection in someone who was previously infected or an infection in a previously not infected individual who was immunized). A retrospective study from Israel during a period of Delta dominance found that the rates of SARS-CoV-2 breakthrough infections in Pfizer-BioNTech vaccinated individuals, while very low (highest rate = 1.5%), were 13 times higher than the rates of reinfection and hospitalization in previously infected individuals, though there was a statistically higher number of individuals in the vaccinated group over age 60 years.⁴⁶ However,

⁴⁴ https://ourworldindata.org/covid-vaccinations?country=OWID_WRL, last accessed July 7, 2022.

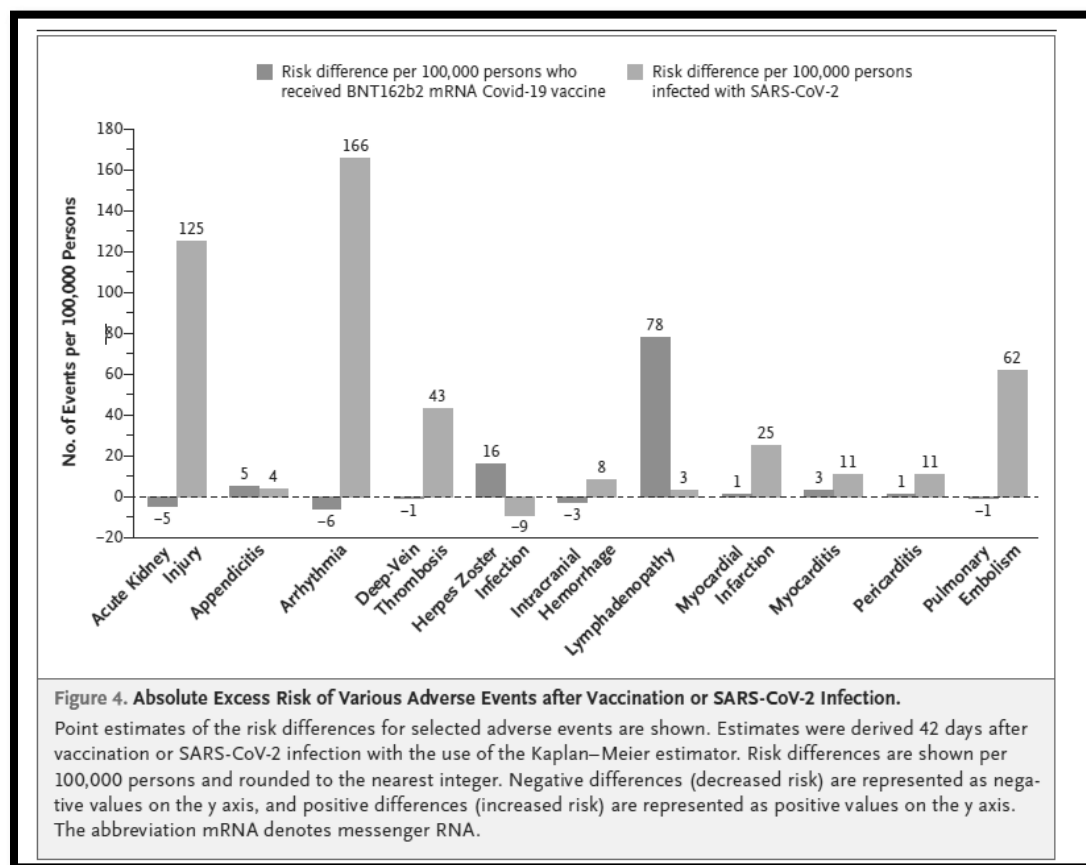
⁴⁵ Ferdinands JM, et al. Waning 2-Dose and 3-Dose Effectiveness of mRNA Vaccines Against COVID-19-Associated Emergency Department and Urgent Care Encounters and Hospitalizations Among Adults During Periods of Delta and Omicron Variant Predominance – VISION Network, 10 States, August 2021-January 2022, <https://www.cdc.gov/mmwr/volumes/71/wr/mm7107e2.html>.

⁴⁶ Gazit S, Shlezinger R et al. SARS-CoV-2 Naturally Acquired Immunity vs Vaccine-induced Immunity, Reinfections versus Breakthrough Infections: a Retrospective Cohort Study. Clin Infect Dis . 2022 Apr 5;ciac262. doi: 10.1093/cid/ciac262

an observational study,⁴⁷ also out of Israel, compared adverse events in 884,828 Pfizer-BioNTech vaccinated matched unvaccinated individuals in addition to comparing those who had a history of COVID-19 disease versus those who did not. As previously identified in multiple studies, vaccination with an mRNA vaccine like Pfizer-BioNTech was associated with an elevated risk of myocarditis compared to those unvaccinated (risk difference 2.7 events/100,000 people). However, when assessing the relative risk in those with a history of COVID-19 disease with those who did not have disease, the risk of myocarditis was substantially higher in those who had COVID-19 disease (risk difference of 11 events/100,000 persons). Additional comparisons between adverse events following COVID-19 vaccine and complications following

⁴⁷ Barda N, et al. Safety of the BNT162b2 mRNA COVID-19 Vaccine in a Nationwide Setting *N Engl J Med* 2021; 385:1078-1090.

COVID-19 disease can also be observed in the following figure.



The Omicron variant

30. On November 26, 2021, the World Health Organization (WHO) designated the Omicron variant (Pango lineage B.1.1.529), first identified in November 2021 in Botswana and South Africa, a “variant of concern” upon recommendations of the Technical Advisory Group on SARS-CoV-2 Virus Evolution, which assesses if specific mutations and combinations of mutations alter the behavior of the virus.⁴⁸ The United States designated Omicron as a variant of

⁴⁸ [https://www.who.int/news/item/26-11-2021-classification-of-omicron-\(b.1.1.529\)-sars-cov-2-variant-of-concern](https://www.who.int/news/item/26-11-2021-classification-of-omicron-(b.1.1.529)-sars-cov-2-variant-of-concern), posted November 26, 2021.

concern on November 30, 2021, and following first detection in the United States on December 1, 2021, it has been found to spread more easily than the original and Delta variants.⁴⁹ Those infected with the Omicron variant in South Africa were initially reported in the media as not having severe outcomes and therefore concluding that this would be a “mild” variant. In attempt to address that misconception, on January 6, 2022, Dr. Tedros Adhanom Ghebreyesus, the WHO Director-General, stated that “while Omicron does appear to be less severe compared to Delta, especially in those vaccinated, it does not mean it should be categorized as ‘mild’. Hospitals are becoming overcrowded and understaffed, which further results in preventable deaths from not only COVID-19 but other diseases and injuries where patients cannot receive timely care. First-generation vaccines may not stop all infections and transmission but they remain highly effective in reducing hospitalization and death from this virus.”⁵⁰

31. Compared to the other COVID-19 variants of concern (Alpha, Beta, Gamma, and Delta), the Omicron variant is the most highly mutated strain, with at least 50 mutations within the genome and at least 32 mutations in the spike protein alone. This can result in increased infectivity and immune escape of the Omicron variant compared with the early wild-type strain and the other four variants of concern.⁵¹ The receptor binding domain (RBD) of the spike protein is what the virus uses to bind to our cells and initiate viral infection process. Antibodies produced from previous infection or vaccination, as well as the monoclonal antibodies (mAb) given to treat those

⁴⁹ <https://www.cdc.gov/coronavirus/2019-ncov/variants/omicron-variant.html>, last accessed July 7, 2022.

⁵⁰ <https://twitter.com/WHO/status/1479167003109859328>, posted January 6, 2022.

⁵¹ Tian D The emergence and epidemic characteristics of the highly mutated SARS-CoV-2 Omicron variant J Med Virol. 2022 Jun;94(6):2376-2383. doi: 10.1002/jmv.27643. Epub 2022 Feb 11.

infected, target the RBD. The degree to which antibodies bind or “neutralize” the virus determines the degree of resultant illness – the better antibodies bind, the less likely a person will become ill. This is why any mutation on the Spike protein RBD would cause concerns about the efficacy of existing vaccines, protection from previous infection, and the mAb given to treat people in preventing Omicron infection.

32. Multiple investigators turned their attention to assessing antibody effectiveness against the Omicron variant in COVID-19 disease survivors compared to vaccine recipients. One study assessed the neutralization of 9 monoclonal antibodies (mAb), sera from 34 COVID-19 vaccine (Pfizer or Astra Zeneca) primary series recipients who had not previously been infected, sera from 20 recipients who had received a Pfizer-BioNTech booster dose, and sera from 40 convalescent sera (blood serum obtained from individuals who had a history of infection) donors, 22 of whom had also been vaccinated.⁵² The better the neutralization, the better the protection. Results showed that the Omicron variant was totally or partially resistant to neutralization by all mAbs tested. Sera from those vaccinated, sampled 5 months after being fully vaccinated, had limited inhibition of the Omicron variant. Blood sera from those with a history of COVID-19 disease demonstrated no or low neutralizing activity against Omicron. Those who received a booster COVID-19 vaccine dose did generate an anti-Omicron neutralizing response, though lower than what has been seen against the Delta variant. A second study⁵³ also demonstrated that those

⁵² Planas, D. et al. Considerable escape of SARS-CoV-2 Omicron to antibody neutralization. *Nature* <https://doi.org/10.1038/s41586-021-04389-z> (2021).

⁵³ Rossler A., et al SARS-CoV-2 Omicron Variant Neutralization in Serum from Vaccinated and Convalescent Persons, *N Engl J Med* 2022; 386:698-700 <https://www.nejm.org/doi/full/10.1056/NEJMc2119236>.

who had a history of infection and were fully vaccinated (whether disease then vaccinated or vaccinated then disease (i.e., a breakthrough infection) were better able to neutralize the Omicron variant as compared to those who had only a history of disease or had a history of being fully vaccinated. An additional small study investigated the neutralizing activity of sera from convalescent patients, mRNA double vaccinated (BNT162b2 = Pfizer-BioNTech; mRNA-1273 = Moderna), mRNA boosted, convalescent double vaccinated, and convalescent boosted individuals against the original SARS-CoV-2 strain, Beta variant (B.1.351), and Omicron (B.1.1.529) variant in a laboratory (in vitro) setting.⁵⁴ In the figures depicted below, Figures 1c–1j provide the results of different combinations of sera studied. What would be interpreted as the “best” combination to work against the Omicron variant is the highest level of red dots on the y-axis seen with the “Omicron” on the x-axis. For example, Figure 1c shows the results of those individuals with a history of COVID-19 disease. In an oversimplified interpretation, Figure 1c shows that those with a history of COVID-19 disease had no measurable neutralizing activity against the Omicron variant. In Figures 1d and 1e, (2 doses of either Pfizer-BioNTech or Moderna), there is some neutralization against Omicron. Those who received a booster (Figure 1f and 1g) had higher levels of neutralization against Omicron compared to the two-dose primary series. Those who had a history of disease and were then vaccinated with a two-dose primary series or a two-dose primary series and a booster (Figures 1h–1j) had better Omicron neutralization. In summary, the study found that neutralizing activity against Omicron “is most impacted in unvaccinated, convalescent individuals and in naïve individuals who acquired immunity through two mRNA COVID-19

⁵⁴ Carreño, J.M., Alshammary, H., Tcheou, J. *et al.* Activity of convalescent and vaccine serum against SARS-CoV-2 Omicron. *Nature* 602, 682–688 (2022). <https://doi.org/10.1038/s41586-022-04399-5> <https://www.nature.com/articles/s41586-022-04399-5>.

vaccine doses” and that “boosted individuals had, at least within the short time after the booster dose, significant protection against symptomatic disease in the range of 75%.”⁵⁵

⁵⁵ *Id.* at 2.

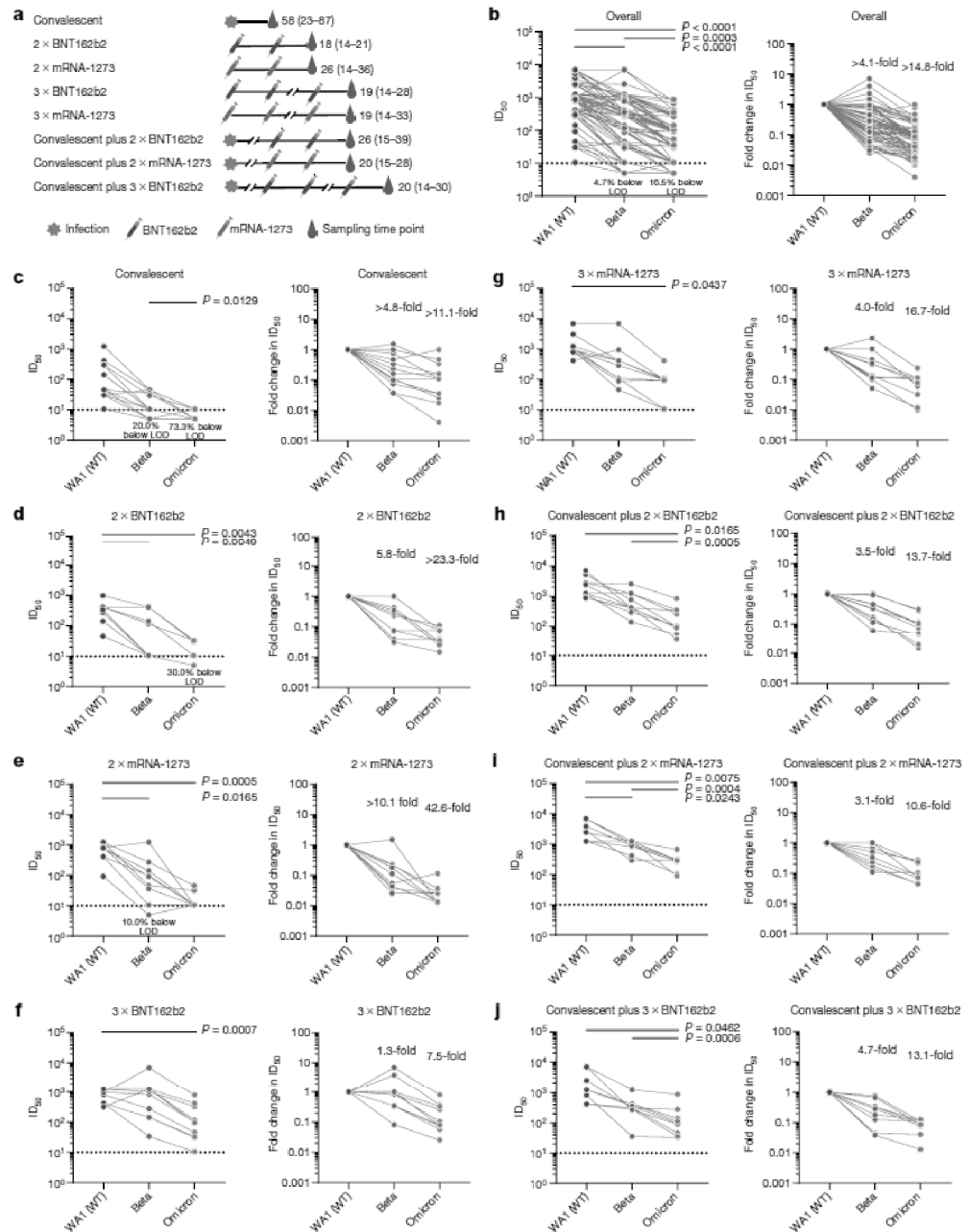
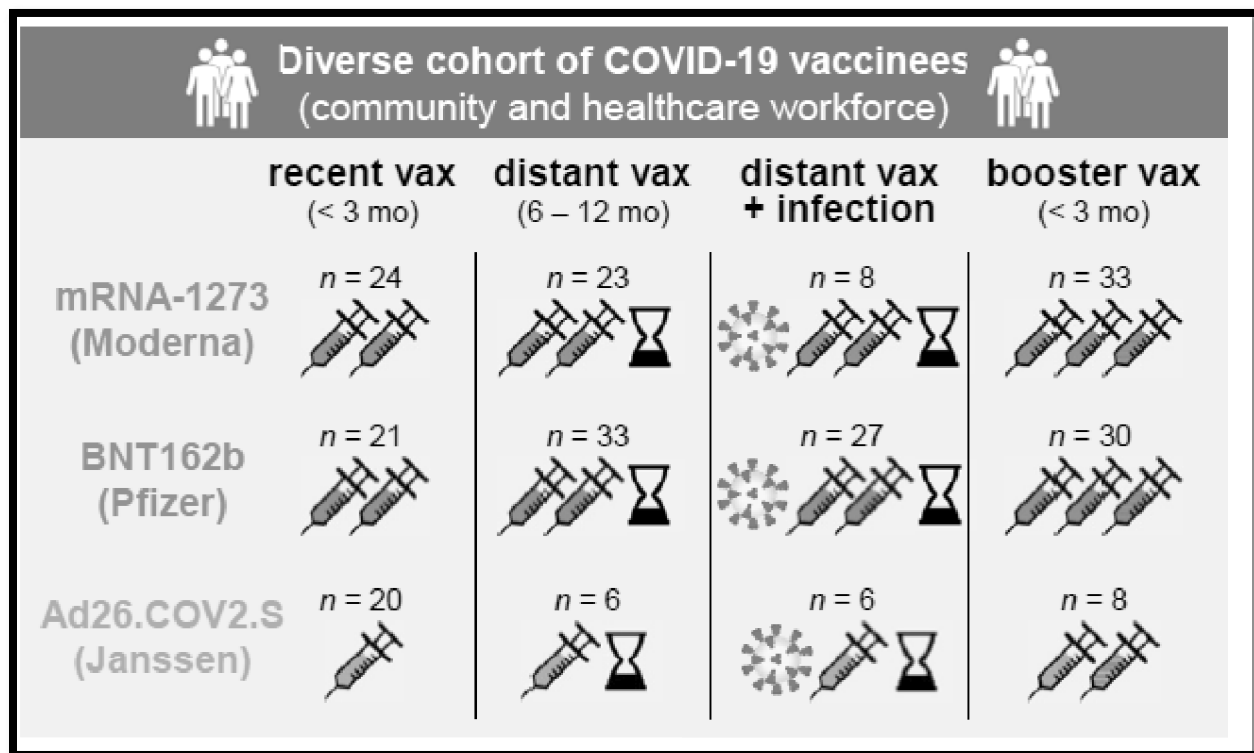


Fig. 1 | Sera from convalescent and vaccinated individuals exhibit strongly reduced neutralizing activity against Omicron compared with wild type SARS-CoV-2. **a**, Overview of different exposure groups from whom samples were obtained. Further details are provided in Supplementary Tables 1, 2. **b**, Absolute titres (left) and fold reduction (right) for neutralization by all serum samples of wild-type (WA1 (WT)), Beta and Omicron SARS-CoV-2 variants. **c–j**, Neutralization of wild-type (WA1 (WT)), Beta and Omicron SARS-CoV-2 variants by sera from convalescent individuals (**c**), after two BNT162b2 vaccinations (**d**), after two mRNA-1273 vaccinations (**e**), after three BNT162b2

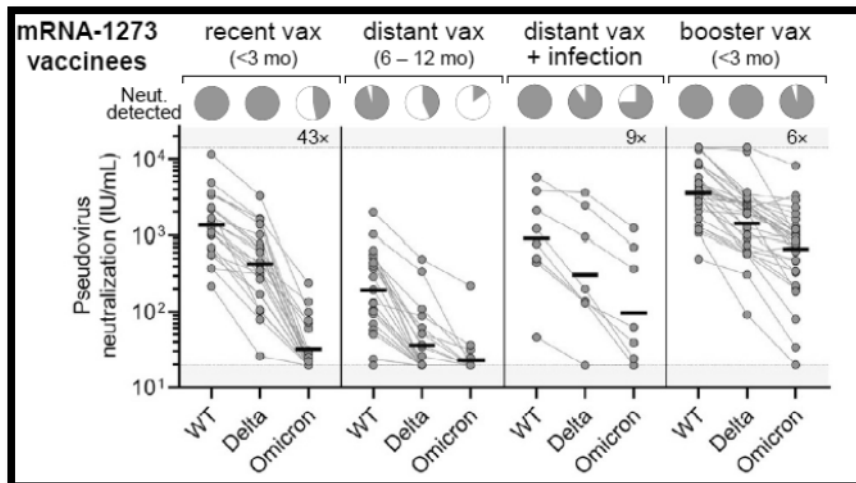
vaccinations (**f**), after three mRNA-1273 vaccinations (**g**), from convalescent individuals after two BNT162b2 vaccinations (**h**), from convalescent individuals after two mRNA-1273 vaccinations (**i**) and from convalescent individuals after three BNT162b2 vaccinations (**j**). One-way ANOVA with Tukey's multiple comparisons test was used to compare the neutralization titres; $P < 0.05$ indicated. $n = 85$ (**b**), 15 (**c**), or 10 (**d–j**) samples. The dotted line represents the limit of detection (10); negative samples were assigned half the limit of detection (5). Each dot represents a biological replicate and the assays were performed once. Fold changes defined as the geometric mean fold change.

33. An additional study⁵⁶ assessed the neutralizing potency of sera from 88 mRNA-1273 (Moderna), 111 BNT162b (Pfizer-BioNTech), and 40 Ad26.COV2.S (Janssen) vaccine recipients against wild-type, Delta, and Omicron COVID-19 variants, based on recent vaccination (< 3 months), distant vaccination (6-12 months), history of infection and distant vaccination, and recent booster vaccination (< 3 months), as depicted below.

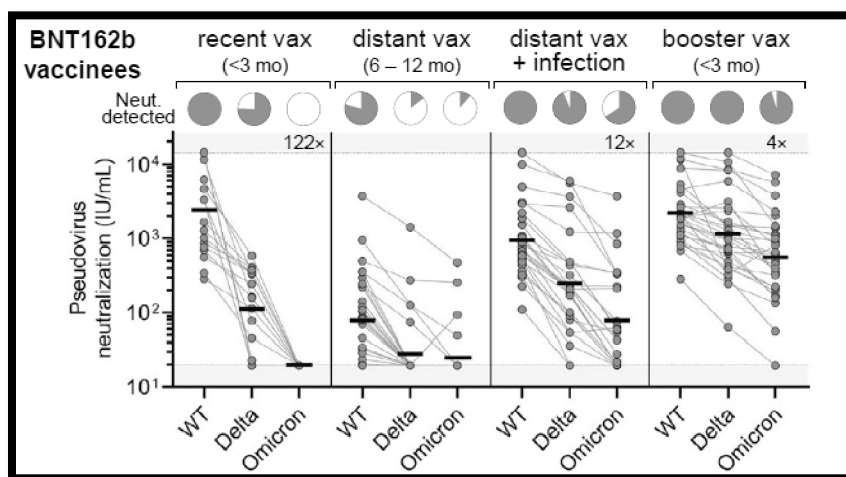


34. Against the Omicron variant, recent (< 3 months) Moderna vaccine recipients exhibited a 43-fold lower neutralization than against the wild type (WT) strain. Those with a history of vaccination and infection had a 9-fold decrease in neutralization than WT, whereas those who received a booster dose less than 3 months ago had a 6-fold decrease in neutralization compared to WT.

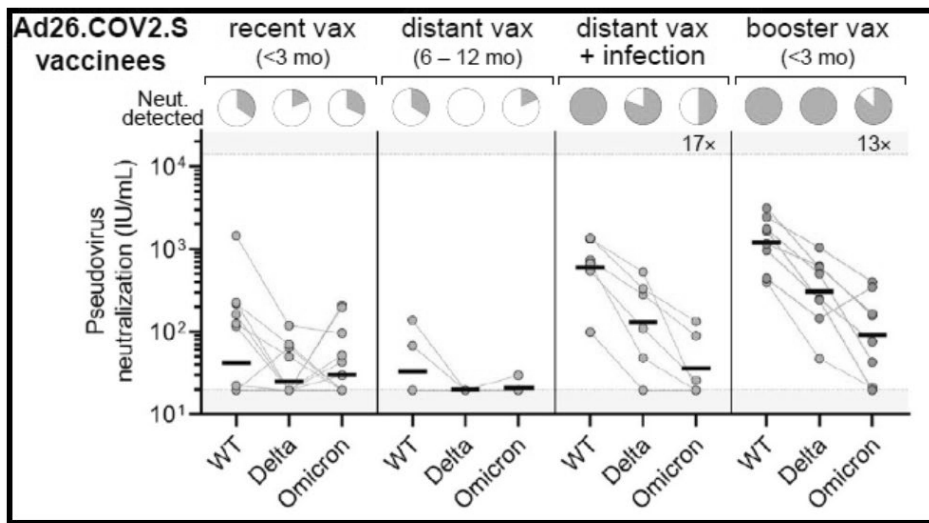
⁵⁶ Garcia-Beltran WF, et al mRNA-based COVID-19 vaccine boosters induce neutralizing immunity against SARS-CoV-2 Omicron variant. *Cell* 2022 Feb 3;185(3):457-466.e4. doi: 10.1016/j.cell.2021.12.033.



35. Similar results were seen in Pfizer-BioNTech recipients, with the best protection against Omicron seen in those who recently received a booster dose.



36. Of the three vaccines, Janssen recipients had the least neutralization against the Omicron variant, with those who recently received a booster dose demonstrating a 13-fold decrease in neutralization as compared to the WT.



37. Finally, two CDC publications described vaccine effectiveness during periods of Delta and Omicron dominance. The first study evaluated the benefit of a third COVID-19 vaccine dose in those who were and were not immunocompromised between August and December 2021. In those who were not immunocompromised vs immunocompromised, vaccine effectiveness (VE) was 82% and 69%, respectively, in those who were fully vaccinated and 97% and 88%, respectively in those who had received 3 doses of COVID-19 vaccine.⁵⁷ The second publication reported on the waning 2- and 3-dose effectiveness of mRNA vaccines against COVID-19 associated emergency department (ED) and urgent care (UC) encounters and hospitalizations among adults during Delta and Omicron between August 2021 and January 2022. During the Delta period, those who sought ED or UC care and received 2 doses versus 3 doses of a mRNA vaccine had an overall VE of 80% and 96%, respectively. Of those admitted to the hospital, COVID-19 VE was 85% and 95%, respectively. During the Omicron period, those who sought

⁵⁷ Tenforde MW, et al., Effectiveness of a Third Dose of Pfizer-BioNTech and Moderna Vaccines in Preventing COVID-19 Hospitalization Among Immunocompetent and Immunocompromised Adults – United States, August-December 2021 Morb Mortal. Wkly Rep 2022;71(4) :118-121. DOI:<https://www.cdc.gov/mmwr/volumes/71/wr/mm7104a2.htm>.

ED or UC care and received 2 doses versus 3 doses of a mRNA vaccine had an overall VE of 41% and 83%, respectively. Those who were admitted to the hospital demonstrated overall VE of 55% and 88%, respectively⁵⁸. Although there was a noticeable decrease in VE during the Omicron period, comparatively mRNA COVID-19 VE is higher than annual influenza vaccine, where VE has ranged between 29-48% over the last 5 seasons.⁵⁹

38. In contrast to the above studies, the CDC recently published a study examining the impact of primary COVID-19 vaccination and previous SARS-CoV-2 infection on COVID-19 incidence and hospitalization rates from California and New York.⁶⁰ The findings demonstrated that prior to Delta variant, being vaccinated with or without a history of COVID-19 resulted in lower incidence of laboratory-confirmed COVID-19 disease and hospitalizations as compared to those who were unvaccinated with a history of disease. However, after the Delta variant became dominant, those with a history of COVID-19 disease, with or without a history of vaccination, had a lower incidence of laboratory-confirmed COVID-19 disease than those who were vaccinated without a history of COVID-19. Excluded in the study was discussion of severity of COVID-19 disease and outcomes of those who had disease (complications, etc.). CDC concludes with reminding readers that more than 130,000 California and New York residents died from COVID-

⁵⁸ Ferdinands JM, et al. Waning 2-Dose and 3-Dose Effectiveness of mRNA Vaccines Against COVID-19-Associated Emergency Department and Urgent Care Encounters and Hospitalizations Among Adults During Periods of Delta and Omicron Variant Predominance – VISION Network, 10 States, August 2021-January 2022. *Morb Mortal. Wkly Rep* 2022;71:1-9. DOI: <https://www.cdc.gov/mmwr/volumes/71/wr/mm7107e2.htm>.

⁵⁹ <https://www.cdc.gov/flu/vaccines-work/past-seasons-estimates.html>, last accessed July 7, 2022.

⁶⁰ Leon TM, Dorabawila V., Nelso L, et al. COVID-19 Cases and Hospitalizations by COVID-19 Vaccination Status and Previous COVID-19 Diagnosis – California and New York, May-November 2021. *Morb Mortal. Wkly Rep* 2022;71:125-131. DOI: <http://dx.doi.org/10.15585/mmwr.mm7104e1>.

19 through November 30, 2021, and that “vaccination remains the safest and primary strategy to prevent SARS-CoV-2 infections, associated complications, and onward transmission.” Moreover, a recent analysis of data from a multistate hospital network on severe COVID-19 outcomes during the Alpha, Delta, and Omicron waves found that “receipt of 2 or 3 doses of a COVID-19 mRNA vaccine conferred 90% protection against COVID-19 associated invasive mechanical ventilation (IMV) or in-hospital death among adults... Among immunocompetent adults with no chronic medical conditions, vaccine efficacy for 2 or 3 doses was 98%... Protection against IMV or death was consistent throughout the Delta and Omicron periods and was higher in adults who received a third vaccine dose, including 94% during the Omicron period.”⁶¹

39. Unvaccinated persons without a history of COVID-19 are most vulnerable to COVID-19 disease. Vaccination was highly effective against the initial SARS-CoV-2 strain it was developed to protect against and continues to be protective against severe disease, hospitalization, and death. The longer the interval from vaccination or natural infection, the increased risk for breakthrough disease. Vaccination and a history of disease was shown to be less protective than vaccination and booster dose against both the Delta and Omicron variants. CDC states “primary COVID-19 vaccination, additional doses, and booster doses are recommended by CDC’s Advisory Committee on Immunization Practices to ensure that all eligible persons are up to date with COVID-19 vaccine, which provides the most robust protection against initial infection, severe illness, hospitalization, long-term sequelae, and death.”⁶²

⁶¹ Mark W. Tenforde, MD, et al. Effectiveness of mRNA Vaccination in Preventing COVID-19-Associated Invasive Mechanical Ventilation and Death – United States, March 2021–January 2022. *MMWR Morb Mortal. Wkly Rep* 2022; 71:459-465. Available at: <https://www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7112e1-H.pdf>.

⁶² Leon TM, Dorabawila V., Nelso L, et al. COVID-19 Cases and Hospitalizations by COVID-19 Vaccination Status and Previous COVID-19 Diagnosis – California and New York, May-

Risks from COVID-19 Vaccination

40. Risks from immunization, including COVID-19 vaccines are rare. CDC provides routine updates on specific adverse events temporally associated with COVID-19 vaccines.⁶³ CDC updates as of July 6, 2022, include the following:

- A. **Anaphylaxis after COVID-19 vaccination is rare** and has occurred in approximately 5 people per million vaccinated in the United States.
- B. **Thrombosis with thrombocytopenia syndrome (TTS) after Johnson & Johnson's Janssen (J&J/Janssen) COVID-19 vaccination is rare** and has occurred in approximately 4 cases per one million doses administered. TTS is a rare but serious adverse event that causes blood clots in large blood vessels and low platelets (blood cells that help form clots). A review of reports indicates a causal relationship between the J&J/Janssen COVID-19 vaccine and TTS.
- C. **Guillain-Barre (GBS) in people who have received the J&J/Janssen COVID-19 vaccine is rare.** GBS is a rare disorder where the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis. Most people fully recover from GBS, but some have permanent nerve damage. GBS has largely been reported in men ages 50 years and older. Based on a recent analysis of data from the Vaccine Safety Datalink, the rate of GBS within the first 21 days following J&J/Janssen COVID-19 vaccination was found to be 21 times higher than after Pfizer-

November 2021. MMWR Morb Mortal. Wkly Rep 2022;71:125-131. January 28, 2022
<http://dx.doi.org/10.15585/mmwr.mm7104e1>.

⁶³ <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html>, last accessed July 7, 2022.

BioNTech or Moderna (mRNA COVID-19 vaccines). After the first 42 days, the rate of GBS was 11 times higher following J&J/Janssen COVID-19 vaccination. The analysis found no increased risk of GBS after Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines).

D. Myocarditis and pericarditis after COVID-19 vaccination are rare. Myocarditis is inflammation of the heart muscle, and pericarditis is inflammation of the outer lining of the heart. Most patients with myocarditis or pericarditis after COVID-19 vaccination responded well to medicine and rest and felt better quickly. Most cases have been reported after receiving Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines), particularly in male adolescents and young adults. A review of vaccine safety data in VAERS from December 2020–August 2021 found a small but increased risk of myocarditis after mRNA COVID-19 vaccines. Over 350 million mRNA vaccines were given during the study period and CDC scientists found that rates of myocarditis were highest following the second dose of an mRNA vaccine among males in the following age groups:

- 12–15 years (70.7 cases per one million doses of Pfizer-BioNTech)
- 16–17 years (105.9 cases per one million doses of Pfizer-BioNTech)
- 18–24 years (52.4 cases and 56.3 cases per million doses of Pfizer-BioNTech and Moderna, respectively)

As of June 30, 2022, there have been 1,011 reports in VAERS among people younger than age 18 years under review for potential cases of myocarditis and pericarditis. Of those, 261 remain under review. Through confirmation of symptoms and diagnostics by provider

interview or review of medical records, 659 reports have been verified. See the following for a breakdown of reports by age group.

- 5-11 years: 22 verified reports of myocarditis after 19,682,799 doses administered
- 12-15 years: 341 verified reports of myocarditis after 23,794,975 doses administered
- 16-17 years: 296 verified reports of myocarditis after 12,951,176 doses administered

Multiple studies and reviews of data from vaccine safety monitoring systems continue to show that vaccines are safe. As the COVID-19 vaccines are authorized for younger children, CDC and FDA will continue to monitor for and evaluate reports of myocarditis and pericarditis after COVID-19 vaccination and will share more information as it becomes available.

E. Reports of death after COVID-19 vaccination are rare. FDA requires healthcare providers to report any death after COVID-19 vaccination to VAERS, even if it's unclear whether the vaccine was the cause. **Reports of adverse events to VAERS following vaccination, including deaths, do not necessarily mean that a vaccine caused a health problem.** More than 596 million doses of COVID-19 vaccines were administered in the United States from December 14, 2020, through June 29, 2022. During this time, VAERS received 15,312 preliminary reports of death (0.0026%) among people who received a COVID-19 vaccine. CDC and FDA clinicians review reports of death to VAERS including death certificates, autopsy, and medical records. Continued monitoring has identified nine deaths causally associated with J&J/Janssen COVID-19 vaccination. CDC and FDA continue to review reports of

death following COVID-19 vaccination and update information as it becomes available.

41. Additionally, on October 27, 2021, the COVID-19 subcommittee of the WHO Global Advisory Committee on Vaccine Safety (GACVS) provided an updated statement regarding myocarditis and pericarditis reported with COVID-19 mRNA vaccines, stating, in part: The GACVS COVID-19 subcommittee notes that myocarditis can occur following SARS-CoV-2 infection (COVID-19 disease) and that mRNA vaccines have clear benefit in preventing hospitalisation and death from COVID-19.⁶⁴ A follow up Joint Statement from the International Coalition of Medicines Regulatory Authorities and World Health Organization in May 2022 reiterates that “the benefit-risk of both of the (mRNA) vaccines remains positive”.⁶⁵ In March 2022, Rosenblum, et al., published United States safety data captured by VAERS reports and v-safe, a new active surveillance system, during the first 6 months of the US COVID-19 vaccination program. During that time, a total of 340,522 VAERS reports were processed following administration of more than 298 million doses of mRNA COVID-19 vaccine. Of these VAERS reports, 313,499 (92.1%) were not serious and managed outside of the hospital setting, 22,527 (6.6%) were serious (defined as inpatient hospitalization, prolongation of hospitalization, permanent disability, life-threatening illness, congenital anomaly or birth defect) and 4,496 (1.3%) were deaths. Over half of the 4,914,583 v-safe participants self-reported local (i.e injection site pain) and systemic (i.e fever) symptoms, most commonly after dose two. COVID-19 vaccine

⁶⁴ <https://www.who.int/news/item/27-10-2021-gacvs-statement-myocarditis-pericarditis-covid-19-mrna-vaccines-updated>, last accessed June 9, 2022.

⁶⁵ <https://www.who.int/news/item/17-05-2022-statement-for-healthcare-professionals-how-covid-19-vaccines-are-regulated-for-safety-and-effectiveness>, last accessed July 7, 2022.

safety monitoring has been the “most comprehensive in US history.”⁶⁶ Most reported adverse events captured by VAERS or v-safe were mild and short in duration. The authors report that the mRNA COVID-19 vaccine post-authorization safety profile that was generally consistent with pre-authorization trials and early post-authorization surveillance reports. They conclude by stating “vaccines are the most effective tool to prevent serious COVID-19 disease outcomes and the benefits of immunisation in preventing serious morbidity and mortality strongly favour vaccination.”⁶⁷

COVID-19 Antibody Tests

42. As described above, testing to assess for acute SARS-CoV-2 infection or serologic testing to assess for prior infection is not recommended for the purposes of vaccine decision-making. Last updated June 14, 2022, the FDA’s In vitro diagnostics EUAs Serology and Other Adaptive Immune Response Tests for SARS-CoV-2⁶⁸ lists approximately 85 products, of which all of them had one of the following three statements about immunity interpretation:

- A. “You should not interpret the results of this test as an indication or degree of immunity or protection from reinfection.”⁶⁹

⁶⁶ Rosenblum HG., et al Safety of mRNA vaccines administered during the initial 6 months of the US COVID-19 vaccination programme: an observational study of reports to the Vaccine Adverse Event Reporting System and v-safe *Lancet Infect Dis.* 2022 Mar 7;S1473-3099(22)00054-8 [https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(22\)00054-8/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(22)00054-8/fulltext).

⁶⁷ *Id.*,

⁶⁸ <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-serology-and-other-adaptive-immune-response-tests-sars-cov-2>, last accessed July 7, 2022.

⁶⁹ <https://www.fda.gov/media/146369/download>, last accessed July 7, 2022.

- B. “It is unknown how long antibodies to SARS-CoV-2 will remain present in the body after infection and if they confer immunity to infection. Incorrect assumptions of immunity may lead to premature discontinuation of physical distancing requirements and increase the risk of infection for individuals, their households and the public.”⁷⁰
- C. “It is unknown how long (IgA, IgM or IgG) antibodies to SARS-CoV-2 will remain present in the body after infection and if they confer immunity to infection. A positive result for XXX test may not mean that an individual’s current or past symptoms were due to COVID-19 infection.”⁷¹

The Continued Need for COVID-19 Vaccination

43. Decreasing COVID-19 infections, hospitalizations, and/or death trends, combined with the lifting of mask mandates, loosening of travel restrictions, and the desire to return to “normal” may indicate to some that there is no longer a need to mandate vaccination or to enforce it. To the contrary, vaccination as recommended by the CDC remains essential to protecting against serious illness, hospitalization, and death, is key to limiting the opportunities for the virus to mutate (thus causing new variants), and is necessary in reducing public risks that could require future safety measures such as travel restrictions and reinstituting public health measures. The COVID-19 landscape just in the past few weeks has tempered some of the excitement of an imminent pandemic exit as cases, hospitalizations, and death rates continue a slow, but steady climb. As a

⁷⁰ <https://www.fda.gov/media/138627/download>, last accessed July 7, 2022.

⁷¹ <https://www.fda.gov/media/137542/download>, last accessed July 7, 2022.

country, we are only 66.8% fully vaccinated and less than 50% of those fully vaccinated have received an indicated booster.⁷² .

44. On April 12, 2022, the Secretary of Health and Human Services renewed the determination that a public health emergency still exists.⁷³

45. Although updated formulations of COVID-19 vaccines concerning more recent variants are undergoing clinical studies at present with encouraging preliminary results, most likely they will not be available, presuming efficacy and safety has been demonstrated to the FDA and CDC, until Fall/Winter 2022. Exiting the COVID-19 pandemic requires global commitment and medical preparedness, particularly in those whose responsibilities, like the military, take them around the world. The Ukraine conflict, where millions of displaced families are congregated in close quarters and under high stress are a prime source for not only COVID-19 infection and other diseases, are a nidus for new COVID-19 variant development and transmission – threats to which our service members, and the partner-nation-forces they work with, will be exposed. The concern of the Omicron variant and subvariants is on full display as Beijing begins its first COVID-19 vaccine mandate on the mainland.⁷⁴ In the US, an increasing number of counties are categorized as having medium [38.1% (+2.64 from last week)] or high [20.73% (+1.26% from last week)] COVID community levels. Other countries are starting to see an uptick in cases as well.⁷⁵ The pandemic is not yet over. Accordingly, the DoD must utilize what is currently available to maintain

⁷² <https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html>, last accessed July 7, 2022.

⁷³ <https://aspr.hhs.gov/legal/PHE/Pages/COVID19-12Apr2022.aspx>, last accessed July 7, 2022

⁷⁴ <https://www.cnn.com/2022/07/07/china/china-covid-beijing-vaccine-mandate-intl-hnk/index.html>, last accessed July 7, 2022

⁷⁵ <https://coronavirus.jhu.edu/data/new-cases>, last accessed June 9, 2022.

the health of its population – and that includes vaccination, our safest most effective preventative and protective measure against severe disease, hospitalization, and death.

46. I am aware that this declaration may be filed in multiple cases for the purpose of defending the Secretary of Defense’s directive to vaccinate Service members against the COVID-19.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on July 10, 2022, in Falls Church, Virginia

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